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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,567	12/08/2003	Joan M. Fallon	8016-4 CON	3060

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,567	FALLON, JOAN M.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61,68,69,72,79 and 80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61,68,69,72,79 and 80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/08/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 61, 68-69, 72 and 79-80 are pending in the application. Although Applicant did not elect an invention *per se*, it is determined that Applicant has elected without traverse via the cancellation of all but one group of invention; namely, a method for treating a symptom of a dysautonomic disorder comprising administration of secretin. This group is deemed to correlate with Group I.

Therefore, the inventions of Groups II and III are withdrawn from the merits as they are directed toward a non-elected invention. All pending claims are directed toward the elected invention.

Claims 61, 68-69, 72 and 79-80 were examined on their merits.

Claim Objections

Claims 68 and 69 are objected to because of the following informalities:

Claim 68 states 'About'. Here, the 'A' in about should be in lower case: 'a'.

Claim 69 states '...secretin top the individual...'. Here, 'top' should read 'to'.

These are considered minor typographical errors.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Please note that US Patent Applications 09/959,092, 09/466,559 and 09/707,395 as well as provisional application 06/224,991 were fully considered with regard to the following 35 U.S.C. 112 First Paragraph rejections since they were incorporated by reference into the Instant Specification.

Claims 58, 68, 69 and 79-80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating hypertension with secretin, does not reasonably provide enablement for a method for treating any dysautonomic disorder such as Parkinson's or Menke's disease or symptom thereof. It is further deemed that the claims are not enabled for treating hypertension in any mammal in any concentration. The specification does not enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to

therapeutic treatments. The standard of enablement is higher for such inventions because effective treatments for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments.

In the Instant case, Applicants have claimed a method for treating any dysautonomic disorders. However, Applicants have not shown working examples wherein secretin would improve *any* symptom of *any* dysautonomic disorder such as paraganglioma tumors, hearing loss, pain, oculogyric crises, ptosis of the eyelids, weight loss, anorexia, bruising or orthostatic hypotension, *inter alia*. The state of the art with regard to dysautonomic disorders is unpredictable. It is known in the art that there are numerous dysautonomic disorders with a wide range of symptoms, and an absolute nexus between these known dysautonomic disorders has yet to be discovered.

The state of the art with regard to secretin efficacy is unpredictable. Some therapeutic properties of secretin have been recently discovered. As discussed by Beck et al. (US 6,020,310), secretin had been used in the past almost exclusively as an evaluation tool in the quantification and examination of gastronomy function (col.4, lines 5-13). Beck et al. *unexpectedly* discovered that secretin had *some* beneficial effects on *some* symptoms of autistic patients (see Table 4 for example, col's 11 & 12).

Although almost all autistic patients display decreased secretin levels, **many dysautonomic disorders do not involve decreased secretin levels**. Because of the unpredictable nature of the diseases, coupled with the unpredictability with using secretin itself, the skilled artisan would necessarily need to perform undue experimentation to determine if secretin actually works effectively toward relieving symptoms of other dysautonomic disorders such as Parkinson's disease or Riley-Day Syndrome and especially with diseases which do not involve secretin dysfunction. Because of the unpredictability of the state of the art, the skilled artisan would perform this experimentation without a reasonable expectation of success.

It has been established that purified secretin does not lower blood pressure in non-hypertensive rats. According to Hoshiko et al. (1994) secretin administered in doses of 5ug/kg/hr, 50 ug/kg/hr and 100 ug/kg/hr did not produce a change in original blood pressure of rats (see Abstract second paragraph). Barlow (1927) further stated; "..new secretin contains a small amount of vasodilatin giving a maximal drop in blood pressure of 8 per cent, while the purified preparation either does not affect the general blood pressure or gives a small pressor reaction" (p. 185). Therefore, the administration of secretin for lowering blood pressure as demonstrated in the Instant specification is considered an unexpected result. However, the unexpected result was achieved only by administration to humans at a dose of at least 1U/kg. It is further noted that Ferring-secretin, as used in the Instant specification, is not known to contain any amount of vasodilatin.

In order to overcome this rejection, a suggestion for rewording claim 1 follows:

A method for treating hypertension in humans, comprising administering to a human in need thereof, 1U/kg of secretin to the human to ameliorate the hypertension.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, ***he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112***; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (emphasis added)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 69 and 79- 80 are rejected under 35 U.S.C. 102(e) as being anticipated by Beck et al. (US 6,197,746).

Beck et al. disclosed treatment of several symptoms of autism via administration of an effective amount of secretin (please see '746 Table 1 for example, and '310 Table 4) thereby anticipating the invention. Beck et al. further taught administration of 'up to 20 clinical units of secretin' (see claim 2 for example). One unit is anticipated by 'up to 20 clinical units' because 'up to 20' includes 'one'. Further, there is no difference between a unit (U) and clinical unit (CU) absent evidence to the contrary. Claim 80 does not materially change the method in that it does not provide any method step. Claim 80 merely recites an 'intended use' of the method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 61, 68-69, 72 and 79-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barlow (1926).

Barlow (1926) demonstrated that secretin, unless highly purified, contains vasodilatin (vasodilator) which lowers blood pressure *in-vivo* (see p. 185, first paragraph). Barlow did not teach administration of secretin to hypertensive subjects.

One of ordinary skill in the art would have been motivated to administer an amount of secretin with a 'small amount of vasodilatin' (as specified by Barlow) to a patient suffering from hypertension in order to lower total blood pressure of the patient. It was clear that secretin containing vasodilatin possessed a blood pressure lowering effect due to its vasodilating properties. Therefore, the ordinary artisan would have had

a reasonable expectation that the combination of secretin and vasodilatin would have successfully lowered blood pressure in a hypertensive patient.

It is noted that the claims state 'comprising administering secretin' which is open language. Because the claims states 'comprising' the method can include administration of additional components such as vasodilatin. In order to overcome this prior art reference, a suggestion is to limit the claim to 'administering a composition consisting of 1U/kg of secretin...'.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

10/25/05